GARY KAYAJANIAN'S AUGUST 11, 2005 ORAL SAB COMMENTS ON ARSENIC* [*PATENT PENDING]

EPA'S PRACTICE WITH RISK ASSESSMENTS IS TO FIND EVIDENCE OF HAZZARD, AS IT DOES HERE WITH HIGH EXPOSURE TO ARSENIC, AND THEN MAKE EVERY EFFORT TO GENERATE HIGH "KILL NUMBERS." IN 2000, EPA EXTRAPOLATED, AND THEREBY MISREAD, THE TAIWAN BLADDER CANCER DATA SET TO ESTABLISH ITS CANCER CLAIM ALTHOUGH WITH VERY MODEST KILL NUMBERS.** [**WITH A MUCH POORER HEALTH CARE SYSTEM, BLADDER CANCER INCIDENCE IN TAIWAN WOULD BE MEASURED AS FATALITIES. SO THE AMERICAN EQUIVALENT OF FOUR (4) BLADDER CANCER DEATHS IN TAIWAN WOULD BE APPROXIMATELY ONE (1) BLADDER CANCER DEATH AND THREE (3) BLADDER CANCERS, NOT THE FOUR (4) DEATHS WITH THE ADD-ON OF ELEVEN (11) EXTRA BLADDER CANCERS THAT EPA CLAIMED.] THIS TIME EPA ASSUMES ITS CANCER CLAIM AND RESORTS TO ANIMAL DATA TO GENERATE A HIGHER RISK CALCULATION.

THE CHARGE QUESTIONS ARE EPA'S EFFORTS TO JUSTIFY THIS USE OF ANIMAL DATA TO REPLACE MORE RELEVANT HUMAN DATA. BY AND LARGE, RESPONDING TO THESE QUESTIONS MAKES NO SENSE. THE THREE-PAGE WRITTEN COMMENTARY I SUBMITTED EARLIER TO THE SAB USES THE SAME TAIWAN BLADDER CANCER DATA EPA RELIED ON IN 2000 TO ESTABLISH A SIGNIFICANTLY LOWER BLADDER CANCER MORTALITY ASSOCIATED WITH "AROUND 50 µg/L" (42-60 µg/L) THAN WITH LOWER ARSENIC EXPOSURES (10-32 µg/L). IN A REFEREED JOURNAL ARTICLE, I ESTABLISH THE SAME POINT USING THE LUNG, LIVER AND BLADDER CANCER MORTALITY DATA FROM THE SAME DATA SET. OTHER DATA I SITE IN THE COMMENTARY AND/OR JOURNAL ARTICLE SUPPORT THE CLAIM THAT "AROUND 50 µg/L" CARRIES A REDUCED TOTAL CANCER MORTALITY OR HEALTH RISK WHEN COMPARED TO LOWER OR HIGHER ARSENIC LEVELS IN WATER.

MODELS AND MECHANISMS ARE MEANT TO EXPLAIN DATA. WHEN THOSE DATA CONTRADICT THE MODELS OR MECHANISMS, THE EXPLANATIONS HAVE NO VALUE. SO, CHARGE TOPICS "A" AND "B," WITH ALL THEIR SUBTEXT SHOULD BE IGNORED.

MANY OF THE CHARGE QUESTIONS IN THE "C" AND "D" SUBSETS FOCUS ON LOW-DOSE RESPONSE EXTRAPOLATIONS. LOW-DOSE EXTRAPOLATION FROM HIGH DOSE DATA, IN HUMANS OR ANIMALS IS CONTRADICTED BY THE REAL HUMAN CANCER DATA "AROUND 50 µg/L" COMPARED TO 10-32 µg/L. SO THOSE SUBSET QUESTIONS MAKE NO SENSE. [AS TO "C2B," THE TAIWAN POPULATION HAS A COMPARATIVELY LARGE SUBGROUP OF YOUNG ADULTS AND CHILDREN.]

QUESTION “C2A” PRESUPPOSES A NEED TO SELECT “A MOST APPROPRIATE CHOICE FOR ESTIMATING RISK IN HUMANS.” THE MORE APPROPRIATE QUESTION (GIVEN THE TAIWAN AND EPA-COLLECTED MILLARD COUNTY, UTAH DATA AVAILABLE) IS, WHICH DATA SET MOST APPROPRIATELY VALUES THE HEALTH BENEFITS ASSOCIATED WITH ARSENIC AROUND 50 µg/L? [ANSWER: FOR WOMEN, THE UTAH DATA SET, BECAUSE IT REPORTS SIGNIFICANT TOTAL CANCER MORTALITY AND OTHER HEALTH EFFECTS. FOR MEN, THE SIGNIFICANT LUNG + LIVER+ BLADDER OBSERVATIONS IN THE TAIWAN DATA SET AND THE HEART DISEASE MORTALITY CITED FROM THE UTAH DATA SET. SIGNIFICANT BENEFITS ARE ASSOCIATED WITH 50 µg/L IN EACH DATA SET. THE SIGNIFICANT FINDINGS IN EACH DATA SET IS MORE RELEVANT TO HUMANS THAN ANIMAL OR PHARMOKINETIC STUDIES.]

THE WATER AND DIETARY INTAKE OF ARSENIC REFERENCED IN D4 AND D5, IF THEY ARE RELEVANT TO THE EPA DISCUSSION, CAN ACCOUNT FOR THE SMALL DISCREPANCY BETWEEN THE TAIWAN AND UTAH DATA SETS: ELEVATED CANCER LEVELS ARE NOTED BETWEEN 10-32 µg/L IN TAIWAN AND 0-25 µg/L IN UTAH – A 25% HIGHER COLLECTIVE WATER AND DIETARY INTAKE OF ARSENIC IN UTAH WOULD ACCOUNT FOR THE DIFFERENCE.

A POSTSCRIPT: EPA HAS USED BLADDER CANCER MORTALITY AND INCIDENCE TO ASSESS RISK. MIGHT IT NOT BE MORE RELEVANT TO FOCUS INSTEAD ON THE MORE RELEVANT ENDPOINT OF “TOTAL CANCER INCIDENCE AND/OR MORTALITY?” IN MILLARD COUNTY TOTAL CANCER MORTALITY IS LOWER IN THE SUBPOPULATION ASSOCIATED WITH 25-<75 µg/L COMPARED TO THE 0-<25 µg/L POPULATION SEGMENT – AND SIGNIFICANTLY LOWER IN WOMEN ($p < 0.000001$).